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Bibliographic Data	
Authors	Amanda M. Hall, Chris G. Maher, Paul Lam, and et al.
Title	Tai Chi Exercise for Treatment of Pain and Disability in People With Persistent Low Back Pain: A Randomized Controlled Trial
PMID	
Citation	Arthritis Care & Research, Vol. 63, No. 11, November 2011, pp 1576–1583
Other information if relevant	The trial was registered on the Australian New Zealand Clinical Trials Registry, No. 12608000270314.

Methods	
Aim of study	To determine the effect of tai chi exercise on persistent low back pain.
Design	Assessor single-blind randomized controlled trial

Participants	
Population from which participants are drawn	All of the subjects were recruited via community advertisements from Sydney, New South Wales, Australia.
Setting (location and type of facility)	All tai chi sessions were conducted at community venues not clinical facilities, such as The George Institute for Global Health, The University of Sydney, and The City of Sydney Ultimo Community Centre within the Sydney metropolitan area.
Age	adults 18 years of age to 70 years, mean age 44.4 years
Sex	41 men, 119 women, total 160 at baseline
Total number of participants for whom outcome data were reported	At the primary endpoint of 10 weeks, 160 participants were analyzed using intention-to-treat analyses. The number tested at follow-up was 75 (94%) in the control group, and 76 (95%) in the tai chi group.
Inclusion criteria	1. Aged 18 to 70 years 2. Required a diagnosis of "nonspecific low back pain $\pm$ leg pain 3. Persistent nonspecific low back pain of $\geq$ 3 months with a minimum level of "moderate" pain or "moderate" activity limitation as determined by the Short Form 36 health survey. 4. Considered appropriate for exercise management of their back pain.
Exclusion criteria	1) Known or suspected serious spinal pathology, 2) any contraindication to exercise, and 3) scheduled for spinal surgery.
Other information if relevant	There were no significant differences between groups in participants' baseline sociodemographic, clinical symptom characteristics, or outcome measure scores. The mean score on the Chronic Pain Grade Scale was 30.1 out of a maximum of 64 points.

Intervention Groups

Group 1	
Group name	Tai chi group
Number in group	80 at baseline
Description of intervention	Tai chi sessions were 40 minutes in duration, including a warm-up and cool down, and were taught by a certified tai chi instructor. They received 18 standardized tai chi sessions over 10 weeks in a group format (2 times per week for 8 weeks followed by once per week for 2 weeks). To improve adherence, participants were sent a weekly reminder of the tai chi class times.
Duration of treatment period	10 weeks
Co-interventions if reported	none
Additional information if relevant	

Group 2	
Group name	Control Group (waitlist)
Number in group	80 at baseline
Description of intervention	Continue with their usual health care defined as their normal general practitioner care or any fitness or health regimen they were currently undertaking. Participants were sent an e-mail by the tai chi instructor during week 5 and week 9 to update them in regard to their followup assessment. At the end of 10 weeks from baseline, they would have the opportunity to attend a subsequent series of tai chi sessions, or receive a free copy of the instructional tai chi DVD.
Duration of treatment period	10 weeks
Co-interventions if reported	none
Additional information if relevant	Continue with their usual care and refrain from starting a new course of treatment.

Primary outcome	
Outcome name and criteria for definition	The primary outcome was bothersomeness of pain symptoms (over the last week) measured using a 0–10 numerical rating scale (NRS) measured 10 weeks after baseline. The minimal clinically important difference (MCID) between groups was set at 1.5 points.
Time points measured and/or reported	At baseline and 10 weeks after baseline by a blinded assessor.
Differences between groups	ITT-analyses showed a statistically significant difference in the change score of the bothersomeness scale between groups at the 10 week follow-up in favor of the tai chi group: 1.7 points (95% CI: 0.9 to 2.5) P value = 0.000. The tai chi group improved significantly by 1.3 points from baseline to the 4 month follow-up while the control group got worse by 0.37 points. The reduction in the bothersomeness of back symptoms met the pre-set MCID of 1.5 points showing a small clinically meaningful effect.

Additional information if relevant	Three participants reported a small initial increase in back pain symptoms that were alleviated by the third or fourth week of treatment, and 1 participant reported an increase in upper back pain that was alleviated once they corrected upper extremity posture. The number tested at follow-up was 75 (94%) in the control group, and 76 (95%) in the tai chi group. Adherence to treatment was defined as attendance at 75% or more of the 18 tai chi sessions and only 28.8% of the treatment group adhered to the intervention. Only 57.5% of the total treatment group attended 50% or more of the tai chi sessions.

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were: 1) average pain intensity over the last week measured using a 0–10 NRS, 2)pain-related disability was measured using 3 standardized disease-specific questionnaires, 3) the Roland-Morris Disability Questionnaire (RMDQ), 4) the Pain Disability Index (PDI), 5) the Quebec Back Pain Disability Scale (QBPDS), 6) the Patient-Specific Functional Scale (PSFS), and the patient's perception of their overall recovery using the 11-point global perceived effect (GPE) scale.
Time points measured	At baseline and 10 weeks after baseline by a blinded assessor.
Differences between groups	Results for all 6 secondary outcomes revealed statistically significant between group mean differences favoring the tai chi group in all instances. Tai chi exercise reduced pain intensity by 1.3 points on a 0–10 scale, and improved self-report disability by 2.6 points on the 0–24 Roland-Morris Disability Questionnaire scale.
Additional information if relevant	The number tested at follow-up was 75 (94%) in the control group, and 76 (95%) in the tai chi group. The followup rate was >90% for all outcomes.

Conclusions	
Key Conclusions Of Study Authors	- This study showed that a 10-week tai chi program improved pain and disability outcomes and can be considered a safe and effective intervention for those experiencing long-term low back pain symptoms. These results were considered a worthwhile treatment effect. - The results support a beneficial effect of tai chi exercise compared to usual care on bothersomeness of pain symptoms, pain intensity, function, and disability. - There was a statistically significant and clinically meaningful between-group difference in the bothersomeness of back pain symptoms. - Seventy five percent of the interviewed participants reported that the treatment effect met their requirements for the smallest worthwhile effect of tai chi for their back pain problems. This is among the first trials to ask participants if they believe the results are worthwhile. - Drop-outs were minimized in the usual care group by offering the participants the opportunity to participate in tai chi at trial conclusion. - The design of the tai chi exercise intervention used in this study incorporated components of strengthening and stretching that previously have been associated with better outcomes for exercise therapy and back pain. - While participants improved with tai chi, typically they did not fully recover. With regard to pain bothersomeness, the group mean for the tai chi group was 3.7 (95% CI 3.2, 4.2) following the intervention and the mean score of pain intensity was 3.4 (95% CI 2.91, 3.8). - The magnitude of the treatment effects on all outcomes for tai chi is similar to that reported for other exercise interventions for chronic low back pain. - Future study designs of tai chi should 1) include a longer-term followup to determine if the observed effects in the current study are also demonstrated over a longer period of time, 2) use another intervention arm to investigate the effects of tai chi compared to other current treatments, 3) assess a broader range of outcomes important in the management of low back pain such as quality of life variables and in particular outcomes that could be assessed by a blinded assessor such as physical activity and function, 4) replicate the study in other patient populations, such as those low back pain patients seeking treatment in primary care.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	The randomization sequence was computer generated (using the random number function in Microsoft Excel) by one of the investigators (CGM) who was not involved in recruitment.
Allocation concealment *(selection bias)*	Low	The treatment codes were placed sequentially into sealed opaque envelopes and thus, allocation sequence was blinded to investigators involved in recruitment.
Blinding of participants and personnel *(performance bias)*	High	Because of the nature of the interventions, it was not possible to blind participants or treatment provider.The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome measures were obtained by an investigator who was unaware of group allocation. The allocation sequence was concealed from the assessor.
Incomplete outcome data *(attrition bias)*	Low	The followup rate was >90% for all outcomes. All participants lost to follow-up were included in the ITT analysis.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with ANZCT.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Tai Chi for Health Program was supported by the Arthritis Foundation of Australia and Arthritis Care of the UK, and adapted by the Arthritis Foundation of the US. Ms Hall's PhD scholarship is supported by an Australian Government Endeavour International Post-Graduate Research Scholarship. Dr. Maher's research fellowship is supported by Australia's National Health and Medical Research Council. Dr. Latimer's Future Fellowship is supported by the Australian Research Council.	
Possible conflicts of interest for study authors	Dr. Lam has received royalties from the instructional DVD *Tai Chi for Back Pain.*	
Notes:		

Comments by DOWC staff

- The findings of this study showed that a 10-week tai chi program was effective for improving pain symptoms and disability compared with usual care controls for those who have chronic low back pain symptoms.

- The between group difference in the bothersomeness symptom scale of 1.7 points after the intervention met the pre-set MCID of 1.5 points showing a small clinically meaningful effect.

- Since the community recruited participants were not typically seeking or receiving care for their back pain problems, it is unclear whether the conclusions are generalized to those who are seeking care for their back pain.

- This study focused on the effectiveness of tai chi compared to usual care. Therefore, the effects of tai chi compared to other interventions are unknown. Tai chi should be compared to other interventions to eliminate the potential risk of introducing attention bias.

- The participants in the tai chi group had an additional eighteen visits with the tai chi instructor compared with the control group, resulting in a potential risk of attention bias. These non-specific effects of added attention in the tai chi group could have influenced the results in favor of the tai chi group that overestimates the treatment effect size.

- Study strengths included the use of an RCT design, a large sample size with adequate statistical power to detect clinically meaningful effects, trial registration, a pre-specified protocol, a defined primary outcome, design features known to minimize bias such as assessor blinding and concealed allocation, an intention-to-treat analysis, and use of a standardized tai chi program and an experienced tai chi practitioner.

- Adherence to treatment was horribly low in the tai chi group. Only 28.8% of the tai chi group attended at least 75% or more of the 18 tai chi sessions. Only 57.5% of the tai chi group attended 50% or more of the tai chi sessions, which means that over 40% of the tai chi group attended less than 9 or half of the tai chi sessions. With this low adherence rate, it is remarkable that the study was still able to show a clinically meaningful effect for tai chi. A separate analysis of just the participants that attained “good adherence” would have undoubtedly shown a greatly increased effect size in favor of tai chi.

- Long-term follow-up beyond the end of treatment was a major limitation in this study. Study effects were observed at short-term followup directly after the 10-week treatment. Therefore, the effects of treatment in the long-term remain unknown.

- The main limitations of the study were lack of blinding of therapists and patients, numerous secondary outcomes, lack of a physical activity assessment, and a low adherence rate in the tai chi group of 29%.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that a 10-week tai chi program was effective for improving pain symptoms and disability compared with usual care controls for those who have chronic low back pain symptoms.

If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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